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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,287	01/25/2002	Peter X. Ma	UMJ-113-B	1860
29296	7590	10/14/2003	EXAMINER	
JULIA CHURCH DIERKER DIERKER & GLASSMEYER, P.C. 3331 W. BIG BEAVER RD., SUITE 109 TROY, MI 48084-2813			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,287	MA ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7&11/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims examined on the merits are 1-21 which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

5 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 (lines 1 and 7), and where recited in other claims,
15 "micro-tubular" and "oriented architecture" (line 8) are uncertain as to meaning and scope in relation to defining the material obtained. It is unclear how micro-tubular differs from being porous, and as to the structure required by having an oriented architecture.

In line 6 of claim 1, "directional temperature gradient" is
20 uncertain as to meaning and how this limitation defines the temperature used.

In line 7 of claim 1, "unnecessary phase" is uncertain as to meaning and scope. Being "unnecessary" is relative and subjective, and it would be uncertain as to when a phase is necessary and not
25 necessary in the claim.

Claims 20 and 21 are confusing by requiring a composition formed by the method of claim 1 since claim 1 does not recite "composition".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

5 A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10 Claims 1, 2, 7-9 and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al (1999) (listed on form 1449).

The claims are drawn to a method of forming a micro-tubular polymeric material by mixing a polymer with a liquid, changing the temperature to cause phase separation, and removing an unnecessary
15 phase to obtain a micro-tubular, porous polymeric material having a predetermined, oriented architecture uniformly throughout.

Zhang et al disclose producing poly(α -hydroxyl acids)/hydroxyapatite porous composite foams by forming a solution containing PLLA or PLGA and hydroxyapatite (HAP), changing the
20 temperature to cause phase separation and removing an unnecessary phase by freezing and drying. For example, see page 447, following "MATERIALS AND METHODS". Further disclosed, page 448, right col, second paragraph, is producing a PLLA foam by solid-liquid phase separation by the procedure used to produce the composite except that
25 HAP is not present. This PLLA foam is described as having an anisotropic tubular morphology with an internal ladder-like structure and parallel channels with each channel having repeating partitions

Art Unit: 1651

with uniform spacing as shown by Fig. 1 (d) on page 449. In view of this description, it appears the PLLA foam obtained by Zhang et al has a micro-tubular, porous structure having a predetermined, oriented architecture uniformly throughout as claimed. There is apparent no
5 step and/or condition in the present specification and claims different than used by Zhang et al that would have produced a structure different than obtained by Zhang et al as shown by Fig. 1 (d). It is noted that the present specification discloses (page 6) that Zhang et al obtain a random architecture. However, Fig. 1 (d) of
10 Zhang et al shows an oriented architecture uniformly throughout the PLLA foam.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- 15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was
20 made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner
25 presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention

was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-6 and 21 are rejected under 35 U.S.C. 103(a) as being
5 unpatentable over Zhang et al (1999).

The claims require the seeding cells on the micro-tubular material formed by the method of claim 1 and culturing the cells on the micro-tubular material.

Zhang et al is described above.

10 It would have been obvious to seed cells on the PLLA foam of Zhang et al and culture the cells for tissue engineering since this a known use for a tissue engineering scaffold made from PLLA as disclosed by Zhang et al (page 446, under "INTRODUCTION").

Claim Rejections - 35 USC § 103

15 Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (1999) in view of Ma et al (1999) (listed on form 1449) and Vacanti et al (6,348,069 B1).

The invention and Zhang et al are described above.

20 Ma et al disclose adding a polymer (PLLA or PLGA) to a liquid, changing the temperature to cause phase separation and removing an unnecessary phase to obtain a porous matrix for use as a scaffold in tissue engineering. See under "Matrix fabrication" (page 61, left col).

Art Unit: 1651

Vacanti et al disclose forming a polymeric matrix scaffold for seeding with cells and implanting to form tissue. The polymer used to form the matrix may be PLGA (col 4, line 10).

It would have been obvious to omit HAP from the process steps of Zhang et al and carry out the process steps without adding HAP to produce a PLLA or PLGA foam having a structure as shown by Fig. 1 (d) as suggested by Ma et al using only PLLA or PLGA and performing the same type of process steps as Zhang et al to obtain a porous matrix for use as a tissue engineering scaffold. Vacanti et al would have further suggested omitting HAP from a disclosure of a scaffold formed only from PLGA (col 4, line 10). Vacanti et al would have also clearly suggested seeding the PLLA or PLGA foam with cells and culturing (paragraph bridging cols 2 and 3). The polymers of claims 10-12 other than PLLA and PLGA are known as an alternative to PLGA for making a scaffold as disclosed by Vacanti et al (col 4, lines 10-20), and the use of these polymers instead of PLLA or PLGA would have been within the skill of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Application/Control Number: 10/057,287

Page 7

Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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David M. Naff
Primary Examiner
Art Unit 1651

10 DMN
10/10/03